

ZANIDIP FILM-COATED TABLETS

Lercanidipine hydrochloride (10mg, 20mg)

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What Zanidip is used for

Zanidip is used to treat high blood pressure also known as hypertension in adults over the age of 18 years (it is not recommended for children under 18 years old)

How Zanidip works

Zanidip belongs to a group of medicines called Calcium Channel Blockers (dihydropyridine derivatives).

Before you use Zanidip

- When you must not use it

- If you are allergic to lercanidipine hydrochloride or any of the ingredients listed at the end of this leaflet
- You have had allergic reactions to drugs closely related to Zanidip tablets (such as amlodipine, nicardipine, felodipine, isradipine, nifedipine or lacidipine)
- If you are suffering from certain heart diseases:
 - Untreated heart failure

- Obstruction to flow of blood from the heart
- Unstable angina (angina at rest or progressively increasing)
- Within one month of heart attack
- You have severe liver or kidney problems
- You are taking drugs that are inhibitors of CYP3A4 isoenzyme:
 - Antifungal medicines (such as ketoconazole or itraconazole)
 - Macrolide antibiotics (such as erythromycin or troleandomycin)
 - Antivirals (such as ritonavir)
- You are taking another drug called ciclosporin or cyclosporin (used after transplants to prevent organ rejection).
- With grapefruit or grapefruit juice.

Do not use if you are pregnant or breastfeeding (see Pregnancy and Breastfeeding section for more information).

- Before you start to use it

Take special care with Zanidip and tell your doctor if:

- You have certain other heart conditions which have not been treated by insertion of a pacemaker or have pre-existing angina
- You have problems with your liver or kidneys or you are on dialysis

- Taking other medicines

It is particularly important to tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This also concerns medicines obtained without a prescription including herbal medicines. Tell your doctor or pharmacist if you are taking any of the following medicines:

- Beta-blockers e.g. metoprolol, diuretics (water tablets) or ACE-inhibitors (medicines to treat high blood pressure)
- Cimetidine (more than 800 mg, a medicine for ulcers, indigestion, or heartburn)
- Digoxin (a medicine to treat a heart problem)
- Midazolam (a medicine that helps you sleep)
- Rifampicin (a medicine to treat tuberculosis)
- Astemizole or terfenadine (medicines for allergies)
- Amiodarone or quinidine (medicines to treat a fast heart beat)
- Phenytoin or carbamazepine (medicines for epilepsy).
Your doctor will want to monitor your blood pressure more frequently than usual.

How to use Zanidip

- How much to use

Always take Zanidip exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Adults: The usual dose is 10 mg film-coated tablet daily at the same time each day. Your doctor may advise you to increase the dose to one

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Zanidip 20 mg film-coated tablet daily, if needed.

The tablets should preferably be swallowed whole with some water.

Elderly: No adjustment of the daily dose is required. However, special care should be exercised in starting treatment

Patients with liver or kidney problems: special care is needed in starting treatment in these patients and an increase in daily dose to 20 mg should be approached with caution.

Children: This medicine should not be used in children under 18 years of age.

If you have any further questions on the use of this product ask your doctor.

- When to use it

It should be taken preferably in the morning at least 15 minutes before breakfast, because a high fat meal significantly increases blood levels of the drug.

- How long to use it

If you stop taking Zanidip your blood pressure may increase again. Please consult your doctor before stopping the treatment.

If you have any further questions on the use of this product, ask your doctor or pharmacist

- If you forget to use it

Do not take a double dose to make up for the forgotten tablet. Take the next tablet at your regular time on the next day. If you are worried about this, talk to your doctor or pharmacist.

- If you use too much (overdose)

If you have taken more Zanidip than you should or if someone else has taken your medicine, tell your doctor or pharmacist or contact your nearest hospital.

Exceeding the correct dosage may cause blood pressure to become too low, and the heart to beat irregularly or faster. It may also lead to unconsciousness.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists, and pharmacists treating you that you are taking Zanidip.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Pregnancy and breast feeding

- Do not take Zanidip if you are pregnant, trying to get pregnant or think you may be pregnant. If you get pregnant while taking Zanidip, stop taking it immediately and contact your doctor.
- Do not take Zanidip if you are breast feeding or plan to breastfeed your baby, because it is not known if the medicine passes into breast milk.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Caution should be exercised because of the possibility of dizziness, weakness and tiredness. Do not drive or use machines until you know how Zanidip affects you.

Taking Zanidip with food and drink

Patients should not consume alcohol during treatment with Zanidip tablets since it may increase the effect of Zanidip tablets

Patients should not take grapefruit or grapefruit juice.

- Things to be careful of

Important information about some of the ingredients of Zanidip

Zanidip contains lactose sugar. If you have been told by your doctor that you have an intolerance to some sugars, talk to your doctor before taking this medicine.

Side effects

Like all medicines, Zanidip can cause side effects, although not everybody gets them.

Uncommon side effects (may affect up to 1 in 100 people):

Headache, dizziness, faster heart beats, palpitations (heart pounding or racing), sudden reddening of the face, neck or upper chest, ankle swelling

Rare side effects (may affect fewer than 1 in 1000 patients):

Sleepiness, feeling sick, vomiting, heartburn, stomach pain, diarrhoea; skin rash, muscle pain, passage of large amounts of urine, tiredness.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835490, or visiting the website nptra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Zanidip

- Storage

Keep this medicine out of the sight and reach of children. Do not use Zanidip after the expiry date which is stated on the carton and the blister after EXP. The expiry date refers to the last day of that month.

Store below 30°C

- Disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Product Description

- What it looks like

Zanidip 10 mg: yellow, circular, biconvex, film-coated tablet scored on one side. The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

Zanidip 20 mg: pink, circular, biconvex, film-coated tablet scored on one side.

- Ingredients

- Active ingredient(s)

lercanidipine hydrochloride 10 mg which is equivalent to 9.4 mg of lercanidipine or lercanidipine hydrochloride 20 mg which is

equivalent to 18.8 mg of lercanidipine.

- Inactive ingredients

lactose monohydrate, microcrystalline cellulose, sodium starch glycolate, povidone K30, magnesium stearate, hypromellose, talc, titanium dioxide (E171), macrogol 6000, and ferric oxide (E172).

- MAL number:

Zanidip 10mg Film Coated Tablets:

MAL20041041AZ

Zanidip 20mg Film Coated Tablets:

MAL07050024AZ

Manufacturer

Recordati Chimica E

Farmaceutica S.P.A.

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Product Registration Holder

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